ATTACHMENT 51

From: Chris G
Sent: Thursday, June 25, 2020 12:23 PM EDT
To: Greg Fiegel
Subject: FW: Request for More Information on Rebotix Repair Repairing/Servicing Activities

From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Thursday, March 19, 2020 1:32 PM
To: Chris G <chris@rebotixrepair.com>
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Request for More Information on Rebotix Repair Repairing/Servicing Activities

Thank you Chris. This is acknowledgment we have received your response to our email request dated March 9, 2020.

Sincerely,

CDR Jitendra Virani
Team Lead

Robotic Assisted Surgical Devices Team
DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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jitendra.virani@fda.hhs.gov

From: Chris G <chris@rebotixrepair.com>
Sent: Thursday, March 19, 2020 1:13 PM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Subject: RE: Request for More Information on Rebotix Repair Repairing/Servicing Activities

Dear Jitendra,

Following are answers to your questions, submitted to us via email on 3-9-20. We feel strongly that the hospital service operations in which we are involved, are safe and effective, as well as conscientious with respect to public health economics.

You refer to 21 CFR 820.3(w) in your introduction. We assume you are referring to the clause that defines the term "remanufacturer". If so, we are confused by this reference since we have only ever seen 21CFR820 applied to a remanufacturer that reprocesses and sells medical devices, as is the case with single use devices which involve sterilization and repackaging. For multiple use devices, many operations such as sharpening and repair, are frequently done by hospitals and third parties. We have never heard of 21CFR820 QSR (which includes design controls) being applied to repair processes performed on multiple use devices or other hospital owned equipment. However, we do believe a formal quality system should be used for all such maintenance.

From the 21 CFR 820.1 Applicability: *"(2) The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico."* In 820.1(a) we also read that: *"This regulation does not apply to manufacturers of components or parts of finished devices".*

Since we supply a service replacement component, and do not manufacture a finished product, we believe this regulation does not apply to us.

Our company did attend the FDA "Public Workshop - Medical Device Servicing and Remanufacturing Activities" (facilitated by Joshua Silverstein) where new potential guidance for service operations was discussed, and feel confident that the service process being discussed here is very consistent with the new ideas being presented for "permissible repairs". However, we (and the hospitals) are trying to understand why this repair is being chosen as a candidate for applying these new regulatory concepts when we have no information of any further activity with the guidance, or any new regulation. If you could help us to understand that we would appreciate it.

Specific to your questions:

1. *What specific devices do you repair? Please provide the device trade names and original manufacturer names.*

Intuitive Surgical, Inc. da Vinci® S EndoWrist® Instruments

2. *For each device, please describe the specific tasks that are conducting as a part of repairing/servicing?*

Each device receives a complete evaluation of all mechanical components along with applicable safety testing of any electrocautery functions, to determine if the device is a suitable candidate for repair. The devices have their proximal housing removed to allow inspection and repair of the simple cable-pulley system inside. There is a PCB inside of the instrument that contains a memory device (off-the-shelf DS2505 IC). This memory device contains the usage counter. The DS2505, which no longer functions for the devices under repair, is replaced by our functional equivalent component. The device receives any necessary maintenance. These repairs are identical to other multiple-use laparoscopic instruments, such as grasper alignment and scissor sharpening. Following reassembly of the proximal housing, the device receives final inspections and safety testing. The device is then checked to verify the original data has been retained and the instrument is fully functional.

3. Are you providing service that may extend the lives of devices beyond the original equipment manufacturer (OEM) stated limit. If yes, please provide information on how many additional uses you extend the lives of the devices and how you confirm it remains safe and effective for its intended use (i.e. the performance and safety specifications are not significantly changed from the original performance and safety specifications).

Yes, hospitals do use this service to operate the instrument beyond the manufacturer's original recommendation, and as we are sure you are aware, this is not at all unusual.

We are confident applying these standard, endoscopic instrument repair processes to the Endowrist instruments, since this is supported by the language below from the 510(k) approval for the EndoWrist instruments:

"Predicate Devices:

The Intuitive SurgicaI Endoscopic Instruments and Tools are substantially equivalent in intended use and/or method of operation to the following predicate devices:

1. *Various Class I Exempt and Class II endoscopic electrocautery surgical instruments including the Baxter Healthcare Endoscopic Instruments (K931340) and the Deknatel Snowden Pencer Diamond Touch™ Brand of Endoscopic Instruments (K.960400)."*

"Device Description:

The working ends and elements of the Intuitive SurgicaJTM Endoscopic Instruments and Accessories are essentially identical in size and shape to the predicate devices referenced and represent standard embodiments of standard surgical tools modified for use with the Intuitive Surgical™ Endoscopic Instrument Control System."

"Comparison to Predicate Device(s):

The Intuitive Surgical™ Instruments are essentially identical in terms of shape, size, function and tissue effect to the standard Class I and II endoscopic instruments cited. Further, the Intuitive Surgical™ Instrument Control System with the additional endoscopic instruments is substantially equivalent to the cleared Intuitive Surgical™ Instrument Control System (K975001)."

These standard and identical surgical tools have been serviced/sharpened/repaired for many years by hospitals all across the USA, and it is true that this often results in a longer life than the manufacturer recommends for a new purchase.

As these devices are multiple-use devices, intended to be cleaned and sterilized by the hospital, the repair process ensures the internal components continue to facilitate proper reprocessing as intended by the OEM. The reprocessing steps for the devices are never altered or intended to be altered.

We do not control uses at the hospital. We simply facilitate the repair/sharpening of their instrument. The hospital decides for each individual instrument based on their evaluation. In fact, it

is very common for instruments to be taken out of service prior to reaching the manufacturer's original recommendation because they are not considered sufficiently sharp to continue use. From our broad experience and understanding, hospitals have always had the responsibility to manage the safety of instruments that they own, including making these kinds of maintenance decisions.

Regarding safety and effectiveness, we believe this repair is quite low on the risk spectrum for medical device service operations, but have performed formal risk management for the aspect of the repair which is related to our component (well beyond state-of-the art for repair processes). The replacement component allows for the resetting of the usage counter ONLY. It is important to note that the small memory device involved is not accessed during the surgical procedure. This information is only accessed during installation onto the host system and prior to the surgeon taking control of the device.

Any instrument being repaired must pass all functional and safety specifications for that devices specific use. For example, a bipolar forcep must pass all standard grasping efficiency tests for a forcep of that size, along with all electrocautery safety and performance testing for that devices rated voltage. A monopolar scissor would have to pass all cutting efficiency tests as well as electrocautery safety and performance testing for its rated voltage.

4. *Do you perform any verification or validation activity(ies) before, during, or after repairing/servicing a device? If so, please describe them. If not, please provide a rationale as to why they are not needed.*

When we perform the service ourselves, the entire process is performed under a formal quality system with validated procedures. When hospitals perform the service, it is done under their quality system. However, we do assist with recommendations and training.

This process includes formal tests of the device as have been determined by a functional evaluation and risk assessment of the repair. We believe our procedures are well above the general standard of practice for similar repair processes. As described above, all aspects of the instrument that could be affected by the repair are fully functionally tested, including appropriate safety tests (such as electrosurgical safety checks).

If considering 21 CFR 820 as a guidance for service operations in general, in Subpart N – Servicing:

(d) Service reports shall be documented and shall include:
(1) The name of the device serviced;
(2) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;
(3) The date of service;
(4) The individual(s) servicing the device;
(5) The service performed; and
(6) The test and inspection data.

These records, including formal test and inspection data, are always documented and retained for each repair done by us for the hospital. Our belief is that hospitals maintain an equivalent record when they perform the repairs.

We would be glad to make ourselves available for a follow-up phone call to discuss this and any other questions you may have about our repair. Thank you.

Sincerely,

Chris Gibson
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From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Monday, March 9, 2020 2:17 PM
To: Chris G <chris@rebotixrepair.com>
Subject: Request for More Information on Rebotix Repair Repairing/Servicing Activities

Dear Chris,

My name is CDR Jitendra Virani and moving forward I will be your FDA contact person for the issues being discussed in the below email chain.

Thank you for your email response dated March 6, 2020. We would like to better understand the activities Rebotix Repair performs as it is important to make sure the repair activities do not significantly change the performance or safety specifications, or intended use as described in 21 CFR 820.3(w). We are asking for more information listed below to confirm that your activities do not require a 510(k) or constitute other regulatory requirements.

1. What specific devices do you repair? Please provide the device trade names and original manufacturer names.

2. For each device, please describe the specific tasks that are conducting as a part of repairing/servicing?

3. Are you providing service that may extend the lives of devices beyond the original equipment manufacturer (OEM) stated limit. If yes, please provide information on how many additional uses you extend the lives of the devices and how you confirm it remains

safe and effective for its intended use (i.e. the performance and safety specifications are not significantly changed from the original performance and safety specifications).

4. Do you perform any verification or validation activity(ies) before, during, or after repairing/servicing a device? If so, please describe them. If not, please provide a rationale as to why they are not needed.

Thank you for continuing to work with us. We look forward to your responses and are happy to discuss any clarifications if needed.

Sincerely,

CDR Jitendra Virani
Team Lead

Robotic Assisted Surgical Devices Team
DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

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From: Chris G <chris@rebotixrepair.com>
Sent: Friday, March 6, 2020 11:59 AM
To: An, Je Hi <Je.An@fda.hhs.gov>; Greg Fiegel <GregFiegel@rebotixrepair.com>
Cc: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Subject: RE: Follow up from FDA

Dear Je Hi,

We are happy to provide a clearer description of our current activities in the marketplace. Following your email, we have reviewed and updated our website to better portray our current activities. The phrase “authorized service centers” is currently irrelevant, as there are no longer any third-party service centers in the USA (we have removed this language from our website). The majority of the servicing entities have been hospital service departments, in which repairs are done internal to the hospital system.

Rebotix Repair carries out two activities in the marketplace:

- Providing a repair component to hospitals to service their instruments, along with instructions and support
- Repair of hospital-owned instruments as a direct service provider to the healthcare institution

There is never any sale or resale of surgical instruments or any other medical device associated with our repair service. There is also never change of ownership. When instruments are repaired outside of the hospital itself, they are carefully tracked by serial number and returned to their original owners. Upon return, they pass through normal processes for similar incoming instruments that temporarily leave the hospital for sharpening, etc.

It is our belief that the original manufacturer, attempting to force a new instrument purchase, is no different than other similar manufacturers encouraging a purchase of new equipment over a repair. Hospitals commonly make safety and efficacy decisions about service operations on medical equipment they own, and we believe our repair service is no different.

We hope that this clarifies our activities and explains our position on why our repair services do not require a 510(k).

Sincerely,

Chris Gibson
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From: An, Je Hi <Je.An@fda.hhs.gov>
Sent: Friday, February 28, 2020 9:19 AM
To: Chris G <chris@rebotixrepair.com>; Greg Fiegel <GregFiegel@rebotixrepair.com>
Cc: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Subject: Follow up from FDA

Dear Chris,

This is a follow up our phone conversation with you on February 28, 2020. I also spoke on the phone on February 20, 2020 with Mr. Greg Fiegel and Mr. Joe Morrison regarding your company's activities and I wanted to follow up with you via email to summarize our conversation.

Your company states on your website www.rebotixrepair.com that your technology allows your authorized service centers to inspect and recondition instruments when the original manufacturers attempts to force a new purchase. Based on this information, we believe that a 510(k) is needed before you continue your operation.

You stated that you would provide further description of your activities (for example, inspection and recondition of instruments) and an explanation of why a 510(k) is not needed by March 6, 2020. Please confirm the receipt of this email.

Should you have any questions, please contact me.

Thank you,

Je Hi

Je Hi An, Ph.D.
Biomedical Engineer

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